EXHIBIT 1

EXHIBIT 1 TO NOTICE OF REMOVAL IDENTIFYING AND ATTACHING DOCUMENTS FROM THE COURT FILE OF THE GENERAL COURT OF JUSTICE, DISTRICT COURT DIVISION, IREDELL COUNTY, NORTH CAROLINA

Exhibit	Documents in State Court File
1(A)	Civil Summons to Merck & Co., Inc. and Merck Sharpe & Dohme Corp., issued on or about October 3, 2017
1(B)	Civil Summons to McKesson Corporation, issued on or about October 3, 2017
1(C)	Plaintiff's Complaint, filed on or about September 5, 2017
1(D)	Receipt for filing fee, dated September 5, 2017

Exhibit 1A

STATE OF NORTH CAROLINA

File No. 17CVD2205

IREDELL County

In The General Court Of Justice
☒ District ☐ Superior Court Division

Name Of Plaintiff	
ROBERT PAYNE	
Address	
277 MITCHELLL TRAIL RD	
City, State, Zip	
STATESVILLE NC 28625	

VERSUS

Name Of Defendant(s)
MERCK & CO., INC. (defendant 1 of 3)
MERCK SHARPE & DOHME, CORP. (defendant 2 of 3)

CIVIL SUMMONS

☐ **ALIAS AND PLURIES SUMMONS (ASSESS FEE)**

G.S. 1A-1, Rules 3 and 4

Date Original Summons Issued	Date(s) Subsequent Summons(es) Issued
3 OCTOBER 2017	

To Each Of The Defendant(s) Named Below:

Name And Address Of Defendant 1	Name And Address Of Defendant 2
MERCK & CO., INC. 2000 GALLOPING HILL ROAD KENILWORTH NJ 07033	MERCK SHARPE & DOHME, CORP. 126 E. LINCOLN AVENUE RAHWAY NJ 07065

A Civil Action Has Been Commenced Against You!

You are notified to appear and answer the complaint of the plaintiff as follows:

1. Serve a copy of your written answer to the complaint upon the plaintiff or plaintiff's attorney within thirty (30) days after you have been served. You may serve your answer by delivering a copy to the plaintiff or by mailing it to the plaintiff's last known address, and
2. File the original of the written answer with the Clerk of Superior Court of the county named above.

If you fail to answer the complaint, the plaintiff will apply to the Court for the relief demanded in the complaint.

Name And Address Of Plaintiff's Attorney (if none, Address Of Plaintiff)	Date Issued	Time
MARC J. BERN & PARTNERS LLP ONE GRAND CENTRAL PLACE 60 EAST 42ND STREET SUITE 950 NEW YORK NY 10165	03 OCTOBER 2017	2:15 ☐ AM ☒ PM

Signature: Patricia Lackey

☒ Deputy CSC ☐ Assistant CSC ☐ Clerk Of Superior Court

☐ ENDORSEMENT (ASSESS FEE)
This Summons was originally issued on the date indicated above and returned not served. At the request of the plaintiff, the time within which this Summons must be served is extended sixty (60) days.

Date Of Endorsement	Time
	☐ AM ☐ PM

Signature

☐ Deputy CSC ☐ Assistant CSC ☐ Clerk Of Superior Court

NOTE TO PARTIES: *Many counties have **MANDATORY ARBITRATION** programs in which most cases where the amount in controversy is $25,000 or less are heard by an arbitrator before a trial. The parties will be notified if this case is assigned for mandatory arbitration, and, if so, what procedure is to be followed.*

(Over)

RETURN OF SERVICE

I certify that this Summons and a copy of the complaint were received and served as follows:

DEFENDANT 1

Date Served	*Time Served*	*Name Of Defendant*
	☐ AM ☐ PM	

☐ By delivering to the defendant named above a copy of the summons and complaint.

☐ By leaving a copy of the summons and complaint at the dwelling house or usual place of abode of the defendant named above with a person of suitable age and discretion then residing therein.

☐ As the defendant is a corporation, service was effected by delivering a copy of the summons and complaint to the person named below.

Name And Address Of Person With Whom Copies Left (if corporation, give title of person copies left with)

☐ Other manner of service *(specify)*

☐ Defendant WAS NOT served for the following reason:

DEFENDANT 2

Date Served	*Time Served*	*Name Of Defendant*
	☐ AM ☐ PM	

☐ By delivering to the defendant named above a copy of the summons and complaint.

☐ By leaving a copy of the summons and complaint at the dwelling house or usual place of abode of the defendant named above with a person of suitable age and discretion then residing therein.

☐ As the defendant is a corporation, service was effected by delivering a copy of the summons and complaint to the person named below.

Name And Address Of Person With Whom Copies Left (if corporation, give title of person copies left with)

☐ Other manner of service *(specify)*

☐ Defendant WAS NOT served for the following reason:

Service Fee Paid	*Signature Of Deputy Sheriff Making Return*
$	
Date Received	*Name Of Sheriff (type or print)*
Date Of Return	*County Of Sheriff*

Exhibit 1B

STATE OF NORTH CAROLINA

IREDELL County

File No. 17CVD2205

In The General Court Of Justice
☒ District ☐ Superior Court Division

Name Of Plaintiff	
ROBERT PAYNE	
Address	
277 MITCHELLL TRAIL RD	
City, State, Zip	
STATESVILLE NC 28625	

VERSUS

Name Of Defendant(s)
MCKESSON CORP. (defendant 3 of 3)

CIVIL SUMMONS

☐ **ALIAS AND PLURIES SUMMONS (ASSESS FEE)**

G.S. 1A-1, Rules 3 and 4

Date Original Summons Issued	Date(s) Subsequent Summons(es) Issued
3 OCTOBER 2017	

To Each Of The Defendant(s) Named Below:

Name And Address Of Defendant 1	Name And Address Of Defendant 2
MCKESSON CORP. 2710 GATEWAY OAKS DR SACRAMENTO CA 95833	

A Civil Action Has Been Commenced Against You!

You are notified to appear and answer the complaint of the plaintiff as follows:

1. Serve a copy of your written answer to the complaint upon the plaintiff or plaintiff's attorney within thirty (30) days after you have been served. You may serve your answer by delivering a copy to the plaintiff or by mailing it to the plaintiff's last known address, and
2. File the original of the written answer with the Clerk of Superior Court of the county named above.

If you fail to answer the complaint, the plaintiff will apply to the Court for the relief demanded in the complaint.

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Signature: Patricia Lackey

☑ Deputy CSC ☐ Assistant CSC ☐ Clerk Of Superior Court

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This Summons was originally issued on the date indicated above and returned not served. At the request of the plaintiff, the time within which this Summons must be served is extended sixty (60) days.

Date Of Endorsement	Time
	☐ AM ☐ PM

Signature

☐ Deputy CSC ☐ Assistant CSC ☐ Clerk Of Superior Court

NOTE TO PARTIES: *Many counties have **MANDATORY ARBITRATION** programs in which most cases where the amount in controversy is $25,000 or less are heard by an arbitrator before a trial. The parties will be notified if this case is assigned for mandatory arbitration, and, if so, what procedure is to be followed.*

(Over)

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☐ As the defendant is a corporation, service was effected by delivering a copy of the summons and complaint to the person named below.

Name And Address Of Person With Whom Copies Left (if corporation, give title of person copies left with)

☐ Other manner of service *(specify)*

☐ Defendant WAS NOT served for the following reason:

DEFENDANT 2

Date Served	*Time Served*	*Name Of Defendant*
	☐ AM ☐ PM	

☐ By delivering to the defendant named above a copy of the summons and complaint.

☐ By leaving a copy of the summons and complaint at the dwelling house or usual place of abode of the defendant named above with a person of suitable age and discretion then residing therein.

☐ As the defendant is a corporation, service was effected by delivering a copy of the summons and complaint to the person named below.

Name And Address Of Person With Whom Copies Left (if corporation, give title of person copies left with)

☐ Other manner of service *(specify)*

☐ Defendant WAS NOT served for the following reason:

Service Fee Paid	*Signature Of Deputy Sheriff Making Return*
$	
Date Received	*Name Of Sheriff (type or print)*
Date Of Return	*County Of Sheriff*

Exhibit 1C

Samy S. Elsherbini
NC Bar No: 51313
MARC J. BERN & PARTNERS, LLP
60 E. 42nd St. Ste 950
New York, New York 10165
Tel: (212) 702-5000
Fax: (212) 818-0164
Attorneys for Plaintiff

IN THE TWENTY-SECOND JUDICIAL DISTRICT, DISTRICT CIVIL COURT

IN AND FOR OF IREDELL COUNTY, NORTH CAROLINA

ROBERT PAYNE,

Plaintiff,

v.

MERCK & CO., INC., a corporation, **MERCK SHARPE & DOHME CORP.**, a corporation; **McKESSON CORP.**, a corporation,

Defendants.

DOCKET NO.: 17CVD2205

CIVIL ACTION

COMPLAINT AND DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiff, by and through his attorneys, MARC J. BERN & PARTNERS LLP, complain and allege against Defendants MERCK & CO., INC., (hereinafter, "Merck"), MERCK SHARPE & DOHME, CORP., and McKESSON CORP., and each of them (collectively, "Defendants"), on information and belief, alleges as follows:

INTRODUCTION

1. Plaintiff brings this action for personal injuries and damages suffered as a direct and proximate result of being inoculated with the unreasonably dangerous vaccine, ZOSTAVAX, intended for the prevention of herpes zoster ("shingles") as manufactured by Defendants.

2. The subject of the present matter is Zostavax, intended for the prevention of shingles. At all times relevant to this action, Defendants developed, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, processed, sold, distributed, and/or marketed Zostavax to be administered to patients throughout the United States, including the State of North Carolina.

3. Plaintiff's claims for damages relate to Defendants' design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of the faulty Zostavax.

4. The Defendants' vaccine that is the subject of this action reached and was administered to Plaintiff, by and through his physician and pharmacy, without substantial change in condition from the time they left Defendants' possession.

5. Plaintiff, his physician, and his pharmacy used Zostavax in the manner in which it was intended.

6. Defendants are solely responsible for any alleged design, manufacture or information defect Zostavax may contain.

7. Defendants do not allege that any other person or entity is comparatively at fault for any alleged design, manufacture, or informational defect regarding Zostavax.

PARTIES

8. Plaintiff ROBERT PAYNE at all times relevant to this action was and is a citizen of the State of North Carolina, residing at 277 Michell Trail Road, Statesville, North Carolina, 28625. Plaintiff was inoculated with Defendants' Zostavax at a CVS Pharmacy, located in Statesville, North Carolina, as recommended for routine adult health maintenance and for the prevention of shingles. The vaccine did not prevent shingles as intended, but rather caused Plaintiff to contract a persistent strain of herpes zoster. On or about June 28, 2016, Plaintiff was treated by Dr. Craig Self, M.D. at Charlotte Eye Ear Nose & Throat Associates, P.A. in Statesville for the onset of a severe vesicular outbreak, accompanied by symptoms of a weakened immune system, which was diagnosed as shingles. Plaintiff experienced persistent symptoms and complications of his condition, and his physician prescribed the drugs gabapentin, valacyclovir, and tramadol in attempts to manage his outbreaks and pain. As a direct and proximate result of these disorders, Plaintiff suffered painful injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, and other damages.

9. At all relevant times to this action, as further detailed herein, Defendants MERCK & CO., MERCK SHARPE & DOHME, AND McKESSON CORP., were engaged in the business of researching, developing, testing, designing, setting specifications for, licensing, manufacturing,

preparing, compounding, assembling, packaging, processing, labeling, marketing, promoting, distributing, selling and/or introducing into interstate commerce and into the State of North Carolina, either directly or indirectly through third parties or related entities, Zostavax, which was to be administered to patients throughout the United States, including North Carolina.

10. Defendant Merck & Co. ("Merck"), is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey. At all times relevant to this action, Merck researched, developed, tested, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, packaged, processed, labeled, marketed, promoted, distributed, and sold Zostavax to be administered to patients throughout the United States, including those in the State of North Carolina. Merck has conducted business and derived substantial revenue from its business activities within the State of North Carolina, including from, but not limited to, its business activities related to Zostavax. Defendant Merck had and continues to have substantial contacts with the State of North Carolina, purposefully availed itself of the privilege of conducting activities and business within the State of North Carolina, derived substantial revenue from its contacts with the State of North Carolina, and its conduct in the State of North Carolina directly relates to Plaintiff's claims in this action. Therefore, Plaintiff's claims arise out of Defendant Merck's contacts with the State of North Carolina.

11. Defendant Merck Sharp & Dohme Corp. is a wholly-owned subsidiary of Defendant Merck and part of the Merck family of companies. Merck Sharp & Dohme Corp. is a corporation organized and existing under the laws of the State of New Jersey with its headquarters located at 126 E. Lincoln Ave., Rahway, New Jersey. At all times relevant to this action, through the actions of its wholly-owned subsidiary, Merck Sharp & Dohme Corp., or, based on information

and belief, its own actions, Merck developed, tested, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, packaged, processed, labeled, marketed, promoted, distributed, and/or sold Zostavax to be administered to patients throughout the United States, including those in the State of North Carolina. Defendant Merck Sharp & Dohme Corp. had and continues to have substantial contacts with the State of North Carolina, purposefully availed itself of the privilege of conducting activities and business within the State of North Carolina, derived substantial revenue from its contacts with the State of North Carolina, and its conduct in the State of North Carolina directly relates to Plaintiff's claims in this action. Therefore, Plaintiff's claims arise out of Defendant Merck Sharp & Dohme Corp.'s contacts with the State of North Carolina.

12. Defendant McKesson Corporation ("McKesson") is a Delaware Corporation with its principal place of business at 2710 Gateway Oaks Boulevard, Sacramento, California. At all relevant rimes, McKesson was in the business of manufacturing, labeling, selling, marketing, packaging, re-packaging, and distributing Zostavax, on information and belief, Zostavax administered to Plaintiff. Defendant does business throughout the United States and in the State of North Carolina, and regularly, continuously, and presently does business with this State, including manufacturing, marketing, selling and distributing Zostavax. Defendant McKesson had and continues to have substantial contacts with the State of North Carolina, purposefully availed itself of the privilege of conducting activities and business within the State of North Carolina, derived substantial revenue from its contacts with the State of North Carolina, and its conduct in the State of North Carolina directly relates to Plaintiff's claims in this action. Therefore, Plaintiff's claims arise out of Defendant McKesson's contacts with the State of North Carolina.

13. Affiliates have provided Merck with support in the development and distribution of Zostavax. McKesson acts as such affiliate and does regularly and continuously conduct business throughout the State of North Carolina, including this County.

14. Based upon information and belief, Merck, either directly or through its agents, servants, and employees, does business in the State of North Carolina, and at all times relevant hereto, has sold and distributed Zostavax in the State of North Carolina.

15. Based on information and belief, Merck advertised Zostavax to patients, healthcare providers, pharmacies, hospitals and/or other medical facilities located throughout the State of North Carolina.

16. Plaintiff was influenced by, affected by, or otherwise caused to use and consent to being inoculated with the Defendants' Zostavax as a result of virtually uniform and/or identical information provided, as well as representations and material omissions made by Defendants Merck, MSD, and McKesson, as set forth herein. This information emanated from the same source, Merck, and was vetted by its copy review department (or equivalent) to ensure uniformity and harmony of the marketing message. The manner by which such information and representations were received by or otherwise exposed to Plaintiff and his healthcare providers was the same and include, but are not limited to, the following:

a. Zostavax applications submitted to and relied upon by FDA for clearance to commercially market the vaccine;
b. Product information, instructions for use, and other labeling materials provided with Zostavax;
c. Marketing and promotional materials made available and provided by Defendants' marketing departments to Plaintiff's healthcare providers, including, but not limited to:
    i. Patient brochures provided by Defendants' sales representatives in person;
    ii. Training seminars hosted by Merck;

iii. Continuing Medical Education ("CME") materials created, authored, and/or provided by Defendants;

iv. Information supplied at Professional Conferences at booths hosted or manned by Merck or their Key Opinion Leaders;

d. Representations and informational packets made and provided by Defendants' marketing and sales departments through their sales representatives Plaintiff's physician during in-office visits or meetings with said physicians and by pharmacies at the places where they go regularly to obtain other medications;

e. Defendants' online websites that provided the same specific information on Zostavax, including product description, indications for use, instructions for use, and ordering information;

f. Zostavax indications for use, as set forth herein. Plaintiff was urged by his healthcare providers to get inoculated with Zostavax for the prevention of adult shingles, which he was informed by said healthcare providers was a dangerous condition; and

g. Plaintiff experienced injuries because of the same defects with Zostavax, which were known or knowable to Defendants, at all relevant times, but negligently, recklessly, and intentionally withheld from Plaintiff and his healthcare providers, as set forth herein.

JURISDICTION AND VENUE

18. Plaintiff, a resident citizen of the State of North Carolina, brings this action pursuant to G.S. 1a-1. Rule 3.

19. This Court has personal jurisdiction over Defendants, Merck and Merck Sharp & Dohme pursuant to G.S. § 1-75.3 and G.S. § 1-75.4 as parties engaged in substantial activity within the State of North Carolina, including acts and omissions that caused or contributed to the harm giving rise to this action, including but not limited to the manufacturing of Zostavax at Defendants' Maurice R. Hilleman Center for Vaccine Manufacturing located in Durham, North Carolina.

20. This Court has personal jurisdiction over Defendant McKesson as a registered agent of Merck, conducting business in the State of North Carolina, pursuant to G.S. § 1-75.3 and G.S. § 1-75.4.

21. Venue is proper in this Court pursuant to G.S. § 1-80 because venue is deemed proper in any county in which the cause of action arose, or in which the corporation usually did business, or has property, or in which any of the plaintiffs reside. A substantial amount of the defendants' conduct, as alleged herein by Plaintiff, took place throughout the State of North Carolina, including within Iredell County.

22. Requiring Defendants to litigate these claims in the State of North Carolina does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

23. Moreover, each Defendant systematically availed themselves of the State of North Carolina by conducting regular and sustained business and engaging in substantial commercial and business activity in the State of North Carolina, including, without limitation, researching, developing, designing, setting specifications for, licensing, manufacturing, preparing, compounding, assembling, processing, marketing, promoting, distributing, selling, and/or introducing into interstate commerce in the State of North Carolina, either directly or indirectly, its products, including Zostavax. Defendants, and each of them, expected or should have expected that their acts would have consequences within the United States, specifically, in the State of North Carolina. Furthermore, Defendants, each of them, derived and, based on information and belief, some Defendants, if not all, continue to derive substantial revenue from their actions, dealings, associations, relationships, or otherwise, as described herein, in connection with Zostavax.

24. Plaintiff's claims arise from and relate to Defendants' purposeful avail of the State of North Carolina because Defendants' wrongful conduct in researching, developing, designing, setting specifications for, licensing, manufacturing, preparing, compounding, assembling, processing, marketing, promoting, distributing, selling, Zostavax took place, in

whole or in part, in the State of North Carolina. Therefore, the claims of Plaintiff relate to and arise from Defendants' explicit contacts and purposeful avail of the State of North Carolina. Further and independently, McKesson Corporation consented to jurisdiction in the State of North Carolina by appointing an agent for service of process in this State and by conducting substantial systematic business in this State.

ALTER-EGO, VICARIOUS AND SUCCESSOR LIABILITY, AND PIERCING THE CORPORATE VEIL AS A RESULT OF THE RELATIONSHIPS BETWEEN MERCK, MERCK SHARPE & DOHME, AND McKESSON CORP.

25. Plaintiff incorporates by reference all prior allegations.

26. At all times herein mentioned, Defendants Merck, Merck Sharp & Dohme, and McKesson were agents, servants, partners, aiders and abettors, co-conspirators, and/or joint venturers, and were all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy, and/or joint venture, and rendered substantial assistance and encouragement to each other, knowing their collective conduct constituted a breach of duty owed to Plaintiff.

27. There exists and, at all times herein mentioned, a unity of interest in ownership between Defendants Merck and Merck Sharp & Dohme such that any individuality and separateness between them has ceased and these particular Defendants are alter-egos. Adherence to the fiction of the separate existence of these particular Defendants as entities distinct from each other will permit an abuse of corporate privilege and would sanction a fraud and/or promote injustice.

28. At all times herein mentioned, Merck, Merck Sharp & Dohme, and McKesson were engaged in the business of, or were successors in interest to, entities in the business of researching,

designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, advertising for sale, and/or selling Zostavax for use by healthcare providers and patients like Plaintiff,. As such, each of these particular Defendants is individually, as well as jointly and severally, liable to Plaintiff for his damages.

29. At all times herein mentioned, the officers and/or directors of Merck and Merck Sharp & Dohme mentioned or referred to herein participated in, authorized, and/or directed the production and promotion of the aforementioned Zostavax when they knew, or with exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by Plaintiff.

30. Plaintiff would not have an adequate remedy if Defendants Merck Sharp & Dohme and McKesson were not named parties in this action.

31. Defendant Merck exercised, and continues to exercise, complete domination of the finances, policy, and business practices of Defendants Merck Sharp & Dohme and McKesson to such an extent that Defendants Merck Sharpe & Dohme and McKesson have no separate minds, wills, or existences of their own.

32. The aforesaid control was used by Defendant Merck to negligently research, design, formulate, compound, test, manufacture, produce, process, assemble, inspect, distribute, market, label, promote, package, prescribe, advertise, and/or sell Zostavax for use by healthcare providers and patients like Plaintiff.

33. As such, there are sufficient grounds, in and of themselves, for disregarding the corporate form and extending liability to Defendants Merck Sharp & Dohme and McKesson through piercing the corporate veil.

34. Based on the foregoing, "Merck" where used hereinafter, shall refer to all subsidiaries, affiliates, divisions, franchises, partners, joint venturers, organizational units of any kind, predecessors, successors, assigns, officers, directors, employees, agents, and representatives of Merck and Merck Sharp & Dohme, and each of them.

35. "Defendants" where used hereinafter, shall refer to all subsidiaries, affiliates, divisions, franchises, partners, joint venturers, organizational units of any kind, predecessors, successors, assigns, officers, directors, employees, agents and representatives of Merck, Merck Sharp & Dohme, and McKesson.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

36. Plaintiff incorporates by reference all prior allegations.

37. Plaintiff is within the applicable statute of limitations for their claims because Plaintiff and his health care professionals did not discover, and could not reasonably discover, the defects and unreasonably dangerous condition of Zostavax.

38. Plaintiff's ignorance of the defective and unreasonably dangerous nature of Zostavax and the causal connection between these defects and each Plaintiff's injuries and resultant damages is due in large part to Defendants' acts and omissions in fraudulently concealing information from the public and misrepresenting and/or downplaying the serious threat to public safety their products present.

39. In addition, Defendants are estopped from relying on any statutes of limitation or repose by virtue of unclean hands, acts of fraudulent concealment, affirmative misrepresentations, and/or omissions.

40. Such conduct includes intentional concealment from Plaintiff, prescribing health care professionals, pharmacies, the general consuming public, and FDA of material information that Zostavax had not been demonstrated to be safe or effective, and carried with them the risks and dangerous defects described herein.

41. Defendants had a duty to disclose the fact that Zostavax was not safe or effective, defective, and unreasonably dangerous, and that being inoculated with Zostavax as a measure of routine health maintenance and prevention carried the above-described risks.

FACTUAL BACKGROUND

42. The National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 et seq. does not preempt Plaintiff from filing this Complaint.

a. Pursuant to § 11(c)(1)(A) of the Vaccine Act, the Vaccine Court has jurisdiction to only hear cases listed on the Vaccine Injury Table.

b. Zostavax is not a vaccine listed in the Vaccine Injury Table. At all times hereinafter mentioned, Merck designed, manufactured, licensed, labeled, tested, distributed, marketed, and sold Zostavax.

43. Zostavax was designed, developed, marketed, and sold with the intended purpose of preventing shingles, which is caused by the varicella zoster virus ("VZV").

44. VZV is a virus that causes chickenpox.

45. Once VZV virus causes chickenpox, the virus remains inactive (dormant) in the nervous system for many years.

46. VZV can be reactivated due to factors such as disease, stress, aging, and immune modulation caused by vaccination. The reactivated VZV infects sensory nerve ganglion and the peripheral nerves and their branches, and persists latently in dorsal root ganglia. Such reactivation causes inflammation of nerve axons as well as vesicular eruptions on skin of involved dermatomes.

47. When reactivated, VZV replicates in nerve cells and is carried down the nerve fibers to the area of skin served by the ganglion that harbored the dormant virus.

48. In May of 2006, the U.S. Food and Drug Administration ("FDA") approved Zostavax to be marketed and sold in the United States by Merck.

49. Zostavax was initially indicated for the "the prevention of herpes zoster (shingles) in individuals 60 years of age and older when administered as a single-dose." FDA Approval Letter, May 25, 2006.

50. FDA approval was based in large part on the results of the SPS supported by Merck.

51. The results of the SPS were published in the *New England Journal of Medicine* on June 2, 2005. The paper was titled "A Vaccine to Prevent Herpes Zoster and Postherpetic Neuralgia in Older Adults." *N. Engl. J. Med.* 2005; 352(22):2271-84.

a. Shingles results from reactivation of latent varicella zoster virus (VZV), which is the virus that causes chickenpox. The incidence and severity of shingles increases as people age.

b. As further described in this paper, "[t]he pain and discomfort associated with herpes zoster can be prolonged and disabling, diminishing the patient's quality of life and ability to function to a degree comparable to that in diseases such as congestive heart failure, myocardial infarction, diabetes mellitus type 2, and major depression." *N. Engl. J. Med.* 2005; 352(22) at 2272.

c. Zostavax is essentially the same vaccine as that used for chickenpox, except significantly stronger.

d. Zostavax contains live VZV. The virulence of the virus is reduced or "attenuated." Attenuated vaccines are designed to activate the immune system with the decreased risk of actually developing the disease.

e. Zostavax is developed from a live attenuated version of the Oka/Merck VZV vaccine strain.

f. One of the paper' s more significant findings was "[t]he greater number of early cases of herpes zoster in the placebo group, as compared with the vaccine group, and the fact that no vaccine virus DNA was detected, indicate that the vaccine did not cause or induce herpes zoster."

52. A risk of using a live virus vaccine is that it is not weakened enough or "under-attenuated".

53. Under-attenuated live virus creates an increased risk of developing the disease the vaccine was to prevent.

54. Under-attenuated live VZV has been shown to reactivate. Leggiadro, R. J. (2000). "Varicella Vaccination: Evidence for Frequent Reactivation of the Vaccine Strain in Healthy Children." *The Pediatric Infectious Disease Journal*, 19(11), 1117–1118; Krause, P. R., & Klinman, D. M. (2000). *Nature Medicine*, 6(4), 451–454.

55. Once injected, attenuated live virus has been shown to recombine into more virulent strains causing disease.

56. Shingles is a reactivation of the latent VZV, that afflicts in nearly 1 million cases annually in the United States, at an occurrence of three to seven times higher incidence in geriatric patients.

57. The approval granted by FDA to allow the selling and marketing of this vaccine came with certain post-marketing commitments that Merck agreed to complete, among other things, to insure the safety of this vaccine. These included the following:

a. A randomized, placebo-controlled safety study to assess the rates of serious adverse events in 6,000 people receiving the vaccine as compared to 6,000 who receive a placebo.

b. An observational study using a health maintenance organization (HMO) and 20,000 vaccinated people to address safety issues in the course of clinical practice. This study is specifically to detect "potential safety

signals following administration of Zostavax." This study was to be submitted to FDA by December 2008.

58. Since the publication of the SPS in the *New England Journal of Medicine*, there have been questions raised regarding the safety of Zostavax in scientific and medical journals.

59. Zostavax is a stronger, more potent version of Merck's live varicella vaccine, ("Varivax") indicated to prevent chickenpox.

60. Varivax contains a minimum of 1,350 plaque-forming units ("PFU") of the virus while Zostavax contains a minimum of 19,400 PFU.

61. In the clinical studies evaluating Zostavax, more than 90% of the vaccinated subjects received 32,300 PFU.

62. Merck added several adverse reactions to its package insert/prescribing information since Varivax was approved.

a. The biological system in which the most adverse reactions were added was the nervous system.

b. Added reactions include: encephalitis, cerebrovascular accident, transverse myelitis, Guillain-Barré syndrome, Bell' s palsy, ataxia, non-febrile seizures, aseptic meningitis, dizziness, and paresthesia.

c. Acute Disseminated Encephalomyelitis is a type of encephalitis.

63. As of July 2012, the patient information sheet, label, and prescribing information distributed with Zostavax contain no clear reference to the potential risk of viral infection.

64. Individuals with compromised immune systems should not receive a live virus vaccine because those individuals can develop the disease that the vaccine is designed to prevent.

65. Instances of zoster virus activation occurs at a rate twenty times higher in immunocompromised patients. Immunocompromised patients encompass a wide spectrum of health conditions ranging from HIV, lymphoma and other cancers, bone marrow transplant recipients, or patients in remission or otherwise who had recently been treated with chemotherapy

or prednisone. For those who may be immunocompromised, the shingles will have atypical manifestations that are attributable to more severe skin legions, increased severity of pain and more diffuse involvement.

66. At all times relevant hereto, the patient information sheet, as well as the label and prescribing information for Zostavax, did not adequately, if at all, address the risk of viral infection. All that was addressed was the concern that a rash and itching might develop at the injection site. This was despite the fact that shingles was a noted occurrence during clinical trials of the vaccine.

67. The prescribing information for Zostavax contains a warning that "[t]ransmission of vaccine virus may occur between vaccines and susceptible contacts."

a. The risk of transmission of vaccine virus is due to active viral infection in individuals receiving Zostavax.

68. Being inoculated with the zoster vaccine too closely to the pneumococcal vaccine ("P23') is known to reduce the immune system's response to the zoster vaccine. Additionally, the CDC states that live-virus attenuated vaccines should not be administered within four weeks of each other. Commonly administered live-vaccines include: measles, mumps and rubella vaccine ("MMR"); rotavirus vaccine; vaccinia vaccine; and the intranasal version of the influenza vaccine ("Flumist") are all in the category of vaccines with potential interactions with Zostavax. Receiving any two of these vaccines too closely together can decrease the efficacy of the zoster vaccine. While the prescribing information furnished by Merck mentions a reduced immune response to Zostavax when coadministered with P23, as of the present, the patient information sheet, label, and prescribing information distributed with Zostavax does not adequately, if at all, address the potential risk of interactions between Zostavax and any of other aforementioned live vaccinations.

69. At all times relevant hereto, the patient information sheet, as well as the label and prescribing information for Zostavax, did not adequately, if at all, address the risk of viral infection or possible diseases of the nervous system. This was despite the fact that Varivax, a less potent vaccine, had added several neurological diseases and symptoms as adverse reactions to the Varivax vaccine.

70. Since Zostavax's introduction in 2006, Vaccine Adverse Event Reports ("VAER") appeared in significant numbers addressing various adverse effects, including, but not limited to, viral infection resulting in disease of the central nervous system, including acute disseminated encephalomyelitis.

71. Documented adverse reactions to vaccines must be reported to the federal government in a compulsory and mandated database, the Vaccine Adverse Event Reporting System ("VAERS".) As of September of 2015, there had been 1,111 submissions received of serious adverse event reports regarding Zostavax, including 36 deaths. These reports included depictions of recurrent instances of myalgia, arthralgia, lymphadenopathy, rash, actinic keratosis, severe cutaneous disease, peripheral neuropathy, cellulitis, herpes keratitis resulting in vision loss, facial paralysis, pneumonia, encephalitis, and death.

72. In addition to postherpetic neuralgia, shingles can lead to other serious complications, such as scarring, bacterial superinfection, allodynia, cranial and/or motor neuron palsies, pneumonia, encephalitis, visual impairment, hearing loss, and death.

73. GlaxoSmithKline ("GSK") has produced an alternative to Zostavax, called Shingrix, which was submitted for approval to FDA in October of 2016, and is expected to be approved in 2017. Unlike Zostavax, which injects a live attenuated virus into the patient, Shingrix

uses a non-live, adjuvant subunit (HZ/su) comprised of glycoprotein E, a protein found on VZV that causes shingles, to enhance the immune response to the antigen.

74. In early state testing, Shingrix has demonstrated clinical efficacy that far surpasses Zostavax, and does not pose any risks of reactivation that a live attenuated vaccine carries. In the phase III trials, Shingrix was 97% effective in preventing shingles in those 50 years and older, and was 89.8% effective for those 70 years and older. Shingrix was also 91% effective in preventing postherpetic neuralgia for patients 50 years and older. In similar sized clinical studies (37,000 tested), the success rate of Zostavax was 51%, whereas Shingrix has efficacy of 91%, with no significant side effects.

75. The Centers for Disease Control and Prevention ("CDC") published that Zostavax wanes in efficacy within five years and has almost no remaining preventative effects after seven years. This fact is not included on any labeling or packaging literature to alert users of decreased efficacy of the vaccine with time.

76. The instructions and information published by Merck regarding Zostavax indicate that only one inoculation is recommended. There is no booster vaccine or recommendation to re-vaccinate. Patients who receive Zostavax do so with the intention to have long-term protection from shingles. However, even upon perfect use, the efficacy of Zostavax will decrease significantly after four years (according to the CDC.)

77. Additionally, unlike the live-attenuated vaccine, Zostavax, non-live alternatives such as Shingrix are safe and effective, even in immunocompromised patients. Non-live vaccines like Shingrix carry no risk of reactivation, which induces shingles after inoculation. Unlike Zostavax, non-live vaccines like Shingrix also maintain efficacy, with an 88% lower risk than Zostavax, which diminishes in efficacy steadily with time, to develop shingles after four years.

78. Merck knew, or should have known, that the pharmaceutical efficacy and overall safety and benefit of a non-live, antigen-protein based vaccine, such as Shingrix, is a safer alternative to Zostavax. The existence of safer alternatives to shingles-preventative care—which is widely known to the scientific community—has been tested in clinical trials alongside Zostavax comparing efficacy. These trials show that the dangers of Zostavax were known or discoverable. Furthermore, GSK has shown that a safer and more effective alternative was known or discoverable with their successful Shingrix trials. Therefore, Merck cannot claim that risks or alternatives were "scientifically undiscoverable" in the context of the state-of-the-art defense.

79. It follows that given the increased risk of viral infection due to vaccination, such complications are also possible complications of Zostavax. It also follows that post-vaccination viral infection can cause significant issues in the nervous system due to the replication of the latent virus in the nervous system.

80. Despite this information and the potential correlation between being administered Zostavax and thereafter developing an infection within a relatively short period of time, leading to the development of shingles or varicella-zoster virus pneumonia, Merck failed to properly address and provide this information both to patients and the healthcare providers prescribing, dispensing, and/or administering Zostavax.

81. As a direct result of Zostavax administration in accordance with the information that Merck provided, Plaintiff suffered, is suffering, and/or will continue to suffer from mental and emotional distress due to resulting physical limitations and seriousness of his condition.

82. As a result of the manufacture, marketing, advertising, promotion, distribution and/or sale of Zostavax, Plaintiff sustained severe and permanent personal injuries. Further, as a tragic consequence of Merck's wrongful conduct, Plaintiff suffered serious, progressive,

permanent, and incurable injuries, as well as significant conscious pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, physical impairment, and injury.

83. Plaintiff has incurred and will continue to incur medical expenses and other economic harm as a direct result of use of Zostavax.

COUNT II:
STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN

84. Plaintiff incorporates by reference all prior allegations.

85. At all relevant times, as set forth, *supra*, Defendants, and each of them, engaged in the business of researching, developing, testing, designing, setting specifications for, licensing, manufacturing, preparing, compounding, assembling, packaging, processing, labeling, marketing, promoting, distributing, selling and/or introducing into interstate commerce Zostavax, and, through that conduct, have knowingly and intentionally placed Zostavax into the stream of commerce with full knowledge that they reach consumers such as Plaintiff, who would be administered the vaccine.

86. Merck had a duty to exercise reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of Zostavax including the duty to take all reasonable steps necessary to manufacture and sell a product that was not defective and unreasonably dangerous to consumers and users of the product.

87. Merck failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of Zostavax because Merck knew, or should have known, that its product caused viral infection, and was therefore not safe for administration to consumers.

88. Merck failed to exercise due care in the labeling of Zostavax and failed to issue to consumers and/or their healthcare providers adequate warnings as to the risk of serious bodily

injury, including viral infection, resulting from its use. Merck failed to exercise due care in the labeling of Zostavax and failed to issue to consumers and/or their healthcare providers adequate warnings as to the risk of serious bodily injury, including viral infection, resulting from its use.

89. Merck failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of Zostavax because Merck knew, or should have known, that its product caused viral infection, and was therefore not safe for administration to consumers.

90. Merck continued to manufacture and market Zostavax despite the knowledge, whether direct or ascertained with reasonable care, that Zostavax posed a serious risk of bodily harm to consumers. This is especially true given its tenuous efficacy.

91. Merck knew, or should have known, that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Merck's failure to exercise ordinary care.

92. As a direct and proximate consequence of Merck's negligence, Plaintiff sustained serious personal injuries and related losses including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, medical and related expenses, and other losses and damages.

COUNT III:
STRICT PRODUCTS LIABILITY: FAILURE TO WARN

93. Plaintiff incorporates by reference all prior allegations.

94. Merck designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed Zostavax.

95. Zostavax was expected to, and did, reach the intended consumers, handlers, and persons coming in contact with the product with no substantial change in the condition in which

the product was designed, produced, manufactured, sold, distributed, labeled, and marketed by Merck.

96. Zostavax was manufactured, designed, marketed, labeled, and sold in a defective condition, for use by Plaintiff's healthcare providers and all other consumers of the product, making the product unreasonably dangerous.

97. Merck researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce Zostavax and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of its product

98. Merck's Zostavax, as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by Merck, was defective due to the product's inadequate warnings and instructions. Merck knew, or should have known, and adequately warned that Zostavax created a risk of serious and dangerous side effects, including but not limited to, viral infection, resulting in shingles, post-herpetic neuralgia, or other diseases of the nervous system.

99. The product was under the exclusive control of Merck and was unaccompanied by appropriate and adequate warnings regarding the risk of severe and permanent injuries associated with its use, including, but not limited to, the risk of developing a disease in the nervous system due to viral infection. The warnings given did not accurately reflect the risk, incidence, symptoms, scope, or severity of such injuries to the consumer.

100. Notwithstanding Merck's knowledge of the defective condition of Zostavax, Merck failed to adequately warn the medical community and consumers of the product, including Plaintiff

and his healthcare providers, of the dangers and risk of harm associated with the use and administration of Zostavax.

101. If Plaintiff was equipped with the knowledge of the defective condition and potential harms of Zostavax, he would not have purchased it and agreed to have it injected into his body.

102. Merck downplayed the serious and dangerous side effects of Zostavax to encourage sales of the product. Consequently, Merck placed its profits above its customers' safety.

103. The product was defective when it left the possession of Merck in that it contained insufficient warnings to alert Plaintiff and/or his healthcare providers to the dangerous risks and reactions associated with it, including possible viral infection of the nervous system or another disease of the nervous system.

104. Even though Merck knew or should have known of the risks and reactions associated with their product, it still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

105. Regulation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.S. 301 to 399 ("FDCA"), requires labels to be revised as soon as there is reasonable evidence of an association of a serious hazard with a drug; thus, a causal relationship need not be proved when revisions to warning labels have been made.

106. On or about March 17, 2017, Merck requested FDA approval and regulatory action to issue a clinical efficacy supplement regarding a change in method of production of Zostavax.

107. Since May 25, 2006, Merck has requested and received approval on thirteen separate occasions to amend, supplement, revise and otherwise change the warning labels, package insert, efficacy data, intended use, and method of production of Zostavax. Each regulatory action

required by or petitioned to FDA is sufficient to overcome the rebuttable presumption that the warning labels of Zostavax are and were adequate.

108. Plaintiff used Merck's Zostavax as intended or in a reasonably foreseeable manner.

109. Plaintiff was not informed of the risk of contracting persistent and chronic shingles, the very condition the vaccine was intended to prevent. Moreover, Plaintiff was not informed of the risk of contracting shingles, post-herpetic neuralgia, residual nerve pain and damage, or herpetic interference into the eyes, and vision loss. Given the knowledge of such risk, Plaintiff would not have voluntarily become inoculated with Zostavax.

110. Merck, as a manufacturer of pharmaceutical products, is held to the level of knowledge of an expert in the field and, further, Merck had knowledge of the dangerous risks and side effects of Zostavax.

111. Plaintiff did not have the same knowledge as Merck and no adequate warning was communicated to his healthcare providers.

112. Merck had a continuing duty to warn consumers of Zostavax, including Plaintiff, of the dangers associated with its product, and by negligently and/or wantonly failing to adequately warn of the dangers of the use of Zostavax, Merck breached its duty.

113. Although Merck knew, or should have known, of the defective nature of Zostavax, it continued to design, manufacture, market, and sell its product without providing adequate warnings and instructions concerning the use of Zostavax so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Zostavax.

114. As a direct and proximate result of Merck's failure to adequately warn or other acts and omissions of Merck described herein, Plaintiff was caused to suffer severe and permanent injuries, pain, and mental anguish, including diminished enjoyment of life.

115. Merck's failure to warn extended beyond the product's label and into other media available to Merck, including, but not limited to, advertisements, person-to-person sales calls, medical journal articles, and medical conference presentations.

116. Upon information and belief, Zostavax, as manufactured and supplied by Merck, was further defective due to inadequate post-market warnings or instructions because after Merck knew, or should have known, of the risk of serious bodily harm from the administration of Zostavax, including, but not limited to, possible viral infection, Merck failed to provide adequate warnings to consumers and/or their healthcare providers about the product, knowing the product could cause serious injury.

117. Zostavax, upon information and belief, as manufactured and supplied by Merck, was defective due to inadequate post-market warnings or instructions when it left Merck's control.

118. As a proximate result of Merck's acts and omissions and Plaintiff's use of Merck's defective product, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses as set forth in Zostavax Complaint, including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, medical bills and other expenses, and other losses and damages.

COUNT IV:
BREACH OF EXPRESS WARRANTY

119. Plaintiff incorporates by reference all prior allegations.

120. Merck, through its officers, directors, agents, representatives, and written literature and packaging, and written and media advertisements, expressly warranted that Zostavax was safe and effective and fit for use by consumers, was of merchantable quality, did not create the risk of or produce dangerous side effects, including, but not limited to, viral infection, and was adequately tested and fit for its intended use.

a. Specifically, Merck stated that "Zostavax is a vaccine that is used for adults 60 years of age or older to prevent shingles (also known as zoster)."

b. Merck also stated that "Zostavax works by helping your immune system protect you from getting shingles."

c. Merck, in its Shingles Prevention Study (SPS) paper, stated that "…the vaccine did not cause or induce herpes zoster."

121. At the time of making such express warranties, Merck knew and/or should have known that Zostavax did not conform to the express warranties and representations and that, in fact, its product was not safe and had numerous serious side effects, including the possibility of viral infection, of which Merck had full knowledge and did not accurately or adequately warn.

122. Zostavax manufactured and sold by Merck did not conform to these representations because it caused serious injury, including diseases of the nervous system and/or viral infection, to consumers such as Plaintiff, when used in routinely administered dosages.

123. Merck breached its express warranties because Zostavax was and is defective for its intended purpose.

124. Plaintiff, through his healthcare providers, did rely on Merck's express warranties regarding the safety and efficacy of their product in purchasing and injecting the product.

125. Members of the medical community, including physicians and other healthcare professionals, relied upon Merck's representations and express warranties in connection with the use recommendation, description, and dispensing of Merck's Zostavax.

126. As a foreseeable, direct, and proximate result of the breach of the express warranties, Plaintiff suffered severe and permanent personal injuries, harm, and economic loss.

COUNT V:
BREACH OF IMPLIED WARRANTY

127. Plaintiff incorporates by reference all prior allegations.

128. At all times relevant to this action, Merck manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, and/or sold Zostavax for use in preventing shingles.

129. Merck knew of the intended use of Zostavax at the time Merck marketed, sold, and distributed its product for use by Plaintiff's healthcare providers, and impliedly warranted the product to be of merchantable quality and safe and fit for its intended use.

130. Merck impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including Plaintiff, and healthcare providers that Zostavax was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

131. Merck's representations and implied warranties were false, misleading, and inaccurate because Zostavax was defective and not of merchantable quality.

132. At the time Merck's product was promoted, marketed, distributed, and/or sold by Merck, Merck knew of the use for which it was intended and impliedly warranted Zostavax to be of merchantable quality and safe and fit for such use.

133. Plaintiff, his healthcare providers, and other members of the medical community reasonably relied on the superior skill and judgment of Merck, as manufacturer, developer, distributor, and seller of Zostavax, as to whether it was of merchantable quality and safe and fit

for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the product was manufactured and sold.

134. Contrary to Merck's implied warranties, Zostavax as used by Plaintiff, was not of merchantable quality and was not safe or fit for its intended use because the product was unreasonably dangerous as described herein.

135. Merck breached its implied warranty because Zostavax was not safely fit for its intended use and purpose.

136. Merck placed Zostavax into the stream of commerce in a defective, unsafe, and inherently dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which it was manufactured and sold.

137. As a foreseeable, direct, and proximate result of Merck's acts and omissions and Plaintiff's use of Merck's defective product, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses to treat and care for their injuries described herein.

COUNT VI:
FRAUDULENT MISREPRESENTATION

138. Plaintiff incorporates by reference all prior allegations.

139. Merck, by and through its agents and employees will be added following discovery, intentionally, willfully, and knowingly, fraudulently misrepresented to the medical community, FDA, and consumers, including Plaintiff and his health care providers, that Zostavax had been adequately tested in clinical trials and was found to be safe and effective.

140. Merck knew or believed at the time it made its fraudulent misrepresentations, that its misrepresentations were false and fraudulent regarding the dangers and risks associated with use of Zostavax. Merck made its fraudulent misrepresentations intentionally, willfully, wantonly,

and with reckless disregard and depraved indifference for the safety and well-being of the users of their product, such as Plaintiff.

141. Merck's fraudulent misrepresentations were made with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also with the intent of inducing the medical community to recommend, prescribe, and dispense, and public to purchase, Zostavax.

142. Merck's fraudulent misrepresentations intentionally concealed the following material information:

a. Merck represented through its labeling, advertising, marketing material, advertisements, and packaging that Zostavax had been tested and was found to be safe and effective for preventing shingles;

b. Merck represented that Zostavax did not cause or induce shingles;

c. Merck knowingly omitted in the packaging for its product that Zostavax can actually cause a viral infection, leading to an array of other infections and/or diseases;

d. Merck represented that Zostavax was safe, when, indeed, it was not.

e. Ann Redfield, MSN, RN, working with the "Vaccine Team" as part of Merck's Clinical Safety and Risk Management Department, wrote the comment section for Merck's WAES*NET adverse event reporting system.

f. Ann Redfield also worked as the "Process Owner" of Merck's Varicella Zoster Vaccine Identification Program. In this capacity, Ann Redfield drafted documents presented to the Merck employees who interacted directly with healthcare providers that recommend, prescribe, and dispense Zostavax. In addition, Ann Redfield gave presentations to Merck's field personnel, which was the sales force of Merck employees who interacted directly with healthcare providers.

g. Upon information and belief, on behalf of Merck, Ann Redfield acted within the scope of her employment when she excluded or otherwise ignored reports of meningitis caused by vaccine-strain herpes zoster and assisted Merck in communicating this false information to sales representatives and then healthcare providers. In the alternative, based upon information and belief, Redfield acted beyond the scope of her employment when she misrepresented key safety information, such as excluding or otherwise ignoring reports of meningitis caused by vaccine-strain herpes zoster in her communications to Merck, who in turn communicated this false information to sales representatives and then health care providers.

143. Merck and Defendants were under a duty to disclose to Plaintiff and his healthcare providers the defective design and formulation of Zostavax, which design and formulation heightened the risk of suffering the injuries, diseases, and maladies more specifically described in this Complaint.

144. Merck had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous injuries and damages to persons who used the product.

145. The intentional concealment and omissions of material fact concerning the safety of Zostavax was undertaken purposefully, willfully, wantonly, and fraudulently by Defendants, with intent to mislead, with reckless disregard for the health and safety of Plaintiff and to induce Plaintiff's healthcare providers to purchase, prescribe, administer, and/or dispense Merck's product; and to mislead Plaintiff into reliance upon Merck's fraudulent misrepresentations to use Merck's product as a safe and effective vaccine.

146. At the time Defendants made these misrepresentations, including Merck through its various officers, directors, agents, representatives, and employees, and at the time Plaintiff was administered Merck's product, Plaintiff was unaware of Defendants' falsehoods, and reasonably believed them to be true.

147. Defendants knew and had reason to know that the product was at great risk of causing serious personal injury to users of the product, and that the product was inherently dangerous in a manner that exceeded the inaccurate and inadequate warnings given by Merck.

148. In reliance upon Defendants' false and fraudulent misrepresentations, through his healthcare providers, Plaintiff was induced to, and did, reasonably rely upon Defendants' misrepresentations regarding the safety and efficacy of Merck's product, thereby sustaining severe

and permanent personal injuries and damages. Defendants knew and had reason to know that Plaintiff, his healthcare providers, in using Merck's product, did not have the ability to determine the true facts intentionally concealed by Defendants, and would not have used the product if the true facts regarding the product had been known by Plaintiff, healthcare providers.

149. As a result of Merck's research and testing or lack thereof, Merck willfully, wrongfully, and intentionally distributed false information including, but not limited to, assuring Plaintiff, the public, and Plaintiff's healthcare providers, that Merck's product was safe for use. As a result of Merck's research and testing, or lack thereof, Merck intentionally omitted, concealed, and suppressed from the medical community, Plaintiff, and other consumers the true results of Merck's studies and research, which revealed the true risks of serious harm associated with the use of the product.

150. Merck had a duty when disseminating information to the public to provide truthful information, and a parallel duty not to deceive the public, including Plaintiff, his healthcare providers, and FDA.

151. The information distributed by Merck to the public, including Plaintiff, the medical community, and FDA, included, but was not limited to, reports, press releases, advertising campaigns, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth regarding the dangers of the use of Zostavax.

152. Merck recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of Zostavax to the public at large, and Plaintiff in particular, for the purpose of influencing the sales of a product known by Merck to be dangerous and defective.

153. Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and purposefully.

154. As a foreseeable, direct, and proximate result of Defendants' described acts and omissions, Plaintiff was caused to suffer the serious and dangerous side effects as are more specifically described in this Complaint.

155. As a direct and proximate consequence of Merck's fraudulent misrepresentations, Plaintiff sustained serious personal injuries and related losses including mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, medical and related expenses, and other losses and damages.

COUNT VII:
NEGLIGENT MISREPRESENTATION

156. Plaintiff incorporates by reference all prior allegations.

157. Merck had a duty to represent the truth accurately and truthfully to the medical community, FDA, and U.S. consumers, including Plaintiff, regarding Merck's claims that Merck's product had been tested, and found to be safe and effective for its stated purposes. The misrepresentations made by Merck, in fact, were false and Merck was careless or negligent in ascertaining the truth of the representations at the time Merck made the misrepresentations.

158. Merck represented and marketed Zostavax as being safe and effective.

159. After Merck became aware of the risks of Zostavax, Merck failed to communicate to Plaintiff and other members of the general public, that the administration of this vaccine increased the risk of viral infection.

160. Merck failed to exercise ordinary care in making representations concerning Zostavax and its manufacture, sale, testing, quality assurance, quality control, and distribution in

interstate commerce. Merck negligently and/or carelessly misrepresented and intentionally concealed the truth regarding the high risk of the Zostavax's unreasonable and dangerous adverse side effects associated with the administration, use, and injection of Zostavax.

161. Merck breached its duty in representing to Plaintiff, his healthcare providers, and the medical community that Zostavax did not carry the risk of serious side effects such as those suffered by Plaintiff and other similarly situated patients.

162. Merck failed to warn Plaintiff and other consumers, of the defective condition of Zostavax, as manufactured and/or supplied by Merck.

163. Merck negligently misrepresented material facts about Zostavax in that it made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Merck made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations.

164. The above misrepresentations were made to Plaintiff as well as the general public.

165. Plaintiff and his healthcare providers justifiably relied on Merck's misrepresentations.

166. Consequently, Plaintiff's use of Zostavax was to their own detriment as Merck's negligent misrepresentations proximately caused Plaintiff's injuries and monetary losses.

167. As a foreseeable, direct, and proximate result of Merck's negligent and/or willful, intentional, and knowing misrepresentations as set forth herein, Merck knew, or had reason to know, that Zostavax had not been sufficiently tested, that it lacked adequate, accurate, and prominent warnings, and that injection with the product created a high risk of adverse health effects, and higher than acceptable risks of harm to users, and higher than reported and represented risks of adverse side effects such as those specifically described herein.

168. As a direct and proximate consequence of Merck's negligent misrepresentations, Plaintiff has sustained serious personal injuries and related losses including mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, medical and related expenses, and other losses and damages.

COUNT VIII:
UNJUST ENRICHMENT

169. Plaintiff incorporates by reference all prior allegations.

170. Merck is and at all times was the manufacturer, seller, and/or supplier of the shingles vaccine, Zostavax.

171. Plaintiff paid for Zostavax for the purpose of preventing shingles.

172. Merck has accepted payment by Plaintiff for the purchase of their product.

173. Plaintiff has not received the safe and effective vaccine for which he paid.

174. It would be inequitable for Merck to keep this money if Plaintiff did not in fact receive safe and effective treatment for the prevention of shingles.

COUNT IX:
STRICT LIABILITY

Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

182. Defendants manufactured, sold, distributed, marketed, and/or supplied Zostavax in a defective and unreasonably dangerous condition to consumers, including Plaintiffs, each of them.

183. Defendants designed, manufactured, sold, distributed, supplied, marketed, and/or promoted Zostavax, which was expected to reach and did in fact reach consumers, including

Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

184. Plaintiff used Zostavax as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendants.

185. Zostavax failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

186. Zostavax was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.

187. Zostavax was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

188. Zostavax was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the propensity to induce herpes zoster or shingles, post herpetic neuralgia, herpes zoster keratitis, vision loss, residual chronic pain, and scarring.

189. Although Defendants knew or should have known of the defective nature of Zostavax, it continued to design, manufacture, market, and sell Zostavax so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by Zostavax.

190. Neither Plaintiff nor his prescribing physicians could have, through the exercise of reasonable care, discovered Zostavax defects or perceived the extent of the dangers posed by the vaccine.

191. As a direct and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severe shingles outbreaks and other painful impediments. In addition, Plaintiff required and will continue to require healthcare and services and Plaintiff has incurred and will continue to incur medical and related expenses as a result of his injuries. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

186. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages under common law and in accordance with North Carolina Law so as to punish Defendants and deter them from similar conduct in the future.

COUNT X:
CONSUMER FRAUD

187. Protection of North Carolina consumers is codified in G.S. §75 in North Carolina Statutes, Chapter 75 for Monopolies, Trusts, and Consumer Protection. The Statute includes broad definitions of advertisement, sale, and trade, to encompass any commercial activity that utilizes unfair methods of competition or deceptive acts or practices relying on false pretenses.

188. In the present matter, Merck engaged in continuous and pointed marketing activity and introduced Zostavax heavily into the stream of commerce within North Carolina and to North

Carolina consumers. Merck engaged in distribution and sales strategy within the state of North Carolina and intended to reach North Carolina consumers, including Plaintiff.

189. The aggressive marketing campaign, containing advertising techniques that evaded divulging the known serious risks and warnings to consumers, including Plaintiff, was unconscionable commercial behavior and is impermissible under the Statute.

COUNT X:
PUNITIVE DAMAGES

190. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

194. Defendant has been repeatedly admonished by FDA about the manner in which it has marketed Zostavax to consumers and healthcare providers.

195. Defendants have repeatedly engaged in a pattern of conduct of deliberately avoiding FDA recommendations as to which warnings relating to public hazards should be included in materials. Defendants have engaged in other similar incidents with other drugs they sell and this evidence tends to show that overstating the benefits of a drug while minimizing the risk of the drug is a pattern and practice of Defendants, which continues even to the present time.

196. Defendants' acts were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiff. Defendants' unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendants in an amount appropriate to punish Defendants, and deter similar conduct in the future.

196. Punitive damages are appropriate under North Carolina law.

WHEREFORE, Plaintiff prays for judgment against Defendants, as follows:

a. For general damages in an amount to be proven at the time of trial;

b. For special damages in an amount to be proven at the time of trial;

c. For statutory damages as set forth above, in an amount to be proven at the time of trial;

d. For exemplary and punitive damages in an amount to be proven at the time of trial, and sufficient to punish Defendant or to deter Defendant and others from repeating the injurious conduct alleged herein;

e. For pre-judgment and post-judgment interest on the above general and special damages;

f. For costs of this suit and attorneys' fees; and

g. All other relief that this Court deems necessary, proper, and just.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly, severally or in the alternative, for compensatory damages, punitive damages and costs of suit as provided by law.

MARC J. BERN & PARTNERS LLP
Attorneys for Plaintiffs

By: Samy S. Elsherbini

For the Firm

Exhibit 1D

IREDELL COUNTY CLERK OF SUPERIOR COURT CIVIL FILING FEES: 17 CVD 002205

File Number _____

Plaintiff (Payor) Payne, Robert

Defendant Merck and Co INC

FLAG "Y"

CVSC	(Superior)	$200
CVDC	(District)	$150
CVAC	(Appeal CVM to District)	$146
CVMC	(Small Claims)	$96 (x____) $_____
CVBC	(Business Court)	$1,300
OSA	(Out of State Attorney)	$225
Iredell Co Sheriff - **22515**		$30(x____) $_____
"M" (LIENS, IRS, NC TAX; $6+) - **21435**		$_____
Conf. Of Judgment - **21400**		$25
Limited Driving Priv. - **24335**		$100 (+$150 CVDC District)
Notice of Hearing on Motion - **21450**		$20

FLAG "N"

CDDC (Divorce)	$225
CVDC (Cust/Qdro/Anul)	$150
21400	
Resume Maiden Name	$10
VSA/Paternity	$6
Registrations ($6+)	$_____
Lis Pendens ($6+)	$_____
Copies - **21410**	$_____
Iredell Co Sheriff - **22515**	$30 (x____) $_____
Facility Fees District - **22220**	$16
Facility Fees Superior - **22120**	$16

TOTAL $ 150.00

DATE 9/5/17

CLERK me

IREDELL COUNTY CLERK OF COURT
M307678 09/05/17 10:43:02
PAYOR: PAYNE,ROBERT
PAYEE: SAME
CASE#: 17CVD002205 VCAP:Y
CITA#:
21220 DC-CIVIL FEES 120.00
21224 DC-CV LAA FEE .95
24681 JUD TECH & FAC 4.00
22220 CO FAC FEE D CV 16.00
TOTAL PAID 150.00
BC TENDERED 150.00
CHANGE .00
5376 ID C48AHB

Revised 8/11/17

IREDELL COUNTY CLERK OF SUPERIOR COURT CIVIL RECEIPTING

File Number_____JA Number_____

RECEIVED OF: _____
(Party paying, not attorney)

PLAINTIFF_____
Address: _____

DEFENDANT_____
Address: _____

FLAG "Y"

JA WRIT - **21430** $25
Possession / Execution

JA Transcript - **21440** $10

Supplemental Proc. - **21400** $_____
(Exec - $30.00)

Trial De Novo - **24310** $100

Out of State Subpoena – **24625** $200
Pro Hac Vice - **24626** $25

Notice of Hearing on Motion - **21450** $20

Iredell Sheriff - **22515** $30 (x___)

Summons - **21455** $15
(A&P and Endorsements)

Business Court – **21122** $1,100

Assign of Judgment (6+) - **21400** $_____

CVSC – Superior Counterclaims $200

CVDC – District Counterclaims $150

CVMC – Magistrate Counterclaims $96

JA JUDGMENTS - **26115** FULL___ PARTIAL___

FLAG "N"

Summary Ejectment Rent Bond - **26220**
Prorated Rent $_____
Rent Amount $_____

26120
BK/ PG Judgment $_____
Book _____ Page_____ Full_____ Partial_____
PSSU, Contempt $_____

26210
Bonds _____ $_____
(Restraining order, appeal bond etc)

21400
BK/PG Writ $_____
Resume Maiden Name $10
Misc (exemplifications/tapes) $_____

Fine - **22700** $_____

Displaced Homemakers - **21610** $55
(Divorce/Supplemental Pleading)

DVO Fund - **21620** $20

Alimony - **26420** $_____

Deposit Until JD - **26600** $_____
(Attachment bonds, claim of liens)

Condemnations - **26130** $_____

Copies - **21410** $_____

Minor Judgment – **26310** $_____

Postage - **24660** $_____

TOTAL $_____

DATE _____

CLERK _____